REMARKS

I. Application Data Sheet

The Examiner points out that in the title of the invention in the Application Data Sheet, the word "Wrinkles" is misspelled. Office Action, page 2. A revised Application Data Sheet is concurrently filed with this paper, correcting this obvious error.

II. English Translation of the Provisional Application

The Examiner also points out that "[t]his application claims benefit to a provisional application No. 60/427,575, filed on November 20, 2002, in a language other than English." *Id.* To satisfy the requirement under 37 C.F.R. § 1.78(a)(5)(iv), Applicant has concurrently filed with this paper an English translation of the provisional application No. 60/427,575 and a statement that the translation is accurate.

III. Objection to the Specification

The Examiner objects to the specification because "A Brief Description of the Drawing is needed in the specification, as required by 37 CFR 1.74" and "SEQ ID NOS need to be inserted after the amino acid sequences at pages 24-27 which are subject to the sequence disclosure rules. See 37 CFR 1.821(d)." Office Action, pages 2-3.

In the present Amendment, a paragraph with a heading of "Brief Description of the Drawing" has been added for Figure 1, the content of which can be found in paragraph [095] in the specification as originally filed.

In addition, "SEQ ID No. 2" has been added after the amino acid sequence for the "acetyl glutamyl-glutamyl-methionyl-glutaminyl-arginyl-arginylamide hexapeptide at 0.05% in water (Argireline from Lipotec)" shown on pages 24-27 of the specification. Support for the amendment can be found in paragraph [044] of the specification as originally filed.

Accordingly, Applicant respectfully requests this objection be withdrawn.

IV. Status of Claims

Claims 1-26 are pending in this application.

In the present Amendment, claims 1, 19, 22, and 24 have been amended. Support for the amendment can be found in the originally filed specification, for example, in paragraphs [056]-[072]. Applicant has not introduced any new matter by the amendments, nor are any estoppels intended thereby.

V. § 102(b) Rejection Over *Montal* as Evidenced by *Ji*

The Examiner rejects claims 1, 13, and 19-21 under 35 U.S.C. § 102(b) as being anticipated by Montal et al. (U.S. Patent No. 6,169,074) ("*Montal*") as evidenced by the Ji et al. article (Diabetes, Vol. 51, pages 1425-1436) ("*Ji*"). Office Action, pages 3-4. Specifically, the Examiner alleges that because the SEQ ID NO:9 disclosed in *Montal* corresponds to SNAP-$25_{187-206}$ and *Ji* teaches that a peptide corresponding to SNAP-$25_{198-206}$ has calcium channel inhibitory activity (citing the abstract), "SEQ ID NO:9 of Montal et al[.] would have been expected inherently to possess calcium-channel inhibitory activity." *Id.* at page 3. The Examiner further alleges that "the [present] claims

do not require the peptide and the calcium-channel inhibitor to be different molecules." *Id.* Accordingly, the Examiner concludes that *Montal* anticipates the rejected claims. *Id.* Applicant respectfully disagrees for at least the following reason.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)) (emphasis added). Further, a rejection under § 102 is proper only when the claimed subject matter is identically described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis added). The identical invention must be described in as complete detail as is contained in, and must be arranged as required by, the claim. M.P.E.P. § 2131.

The Examiner has failed to establish that each and every element in claims 1, 13, and 19-21 as amended is either expressly or inherently described in *Montal*. Specifically, *Montal* does not expressly or inherently teach the combination of the (1) at least one peptide and the (2) at least one calcium-channel inhibitor, wherein the at least one calcium-channel inhibitor is different from the at least one peptide as presently claimed in, for example, Claim 1 as amended.

Therefore, Applicant respectfully requests this rejection be withdrawn.

VI. § 103(a) Rejection Over *Montal* as Evidenced by *Ji*

The Examiner rejects claims 8-11 and 14 under 35 U.S.C. § 103(a) as being obvious over *Montal* as evidenced by *Ji*. Office Action, pages 4-5. Specifically, the Examiner relies on the allegations made in the 102(b) rejection set forth above, but

admits that *Montal* does not "teach concentrations for the components of the disclosed pharmaceutical compositions." *Id.* at page 4. To remedy this deficiency, the Examiner alleges that "[i]t would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations." *Id.* at pages 4-5. Applicant respectfully disagrees for at least the following reason.

To establish a *prima facie* case of obviousness, three basic criteria must be met, including that the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143.

Here, the Examiner has failed to point to any evidence showing that the cited references teach or suggest the combination of the (1) at least one peptide and the (2) at least one calcium-channel inhibitor, wherein the at least one calcium-channel inhibitor is different from the at least one peptide as presently claimed in, for example, Claim 1 as amended. Therefore, as the Examiner has failed to establish a *prima facie* case of obviousness, Applicant respectfully requests this rejection be withdrawn.

VII. § 103(a) Rejection Over *Besne*

The Examiner rejects claims 1-5 and 8-26 under 35 U.S.C. § 103(a) as being obvious over Besne (U.S. Patent Application Publication No. 2003/0235599) ("*Besne*"). Office Action, pages 5-6. Specifically, the Examiner states that *Besne* teaches compositions for smoothing out expression wrinkles and fine lines in the skin, which "are required to comprise a sapogenin," a dermo-relaxant. *Id.* at page 5. The Examiner further states that the compositions disclosed in *Besne* "can comprise muscle relaxants such as alverine and its salts, manganese gluconate, and the hexapeptide Argireline.

See, e.g., the Abstract, paragraphs [0019], [0031], [0033], [0071], and [0090]; Example 2; and claim 8. Argireline has the same amino acid sequence as Applicant's SEQ ID:2" *Id.* The Examiner admits that "Besne does not teach compositions comprising multiple muscle relaxants, i.e. comprising the hexapeptide Argireline plus at least one of alverine and it[s] salts or manganese gluconate." *Id.* However, the Examiner alleges that it would have been obvious to form compositions comprising "the hexapeptide Argireline plus at least one of alverine and it[s] salts or manganese gluconate" "according to Besne comprising multiple muscle relaxants," "because Besne discloses all three components to be useful in the wrinkle-treating compositions, [and] because it is prima facie obvious to use a mixture of components each of which has been used individually for the same purpose," *i.e.*, "smoothing out expression wrinkles and fine lines in the skin" (citing *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980)). *Id.* Applicant respectfully disagrees for at least the following reasons.

To establish a *prima facie* case of obviousness, three basic criteria must be met, including that there is some suggestion or motivation, either in the cited reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. M.P.E.P. § 2143. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 1998) (citations omitted). The teaching or suggestion to modify must be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Here, the Examiner has failed to point to any evidence of a suggestion or motivation to form the presently claimed composition based on the teachings of *Besne* as alleged by the Examiner. As stated by the Examiner, *Besne* discloses a composition comprising sapogenin as a required component. What the Examiner neglects to focus on, however, is that *Besne* also teaches "sapogenin and/or sapogenin ester are used as agents for the smoothing out wrinkles and fine lines, in particular expression wrinkles and fine lines." Abstract; paragraphs [0002] and [0019]. Thus, given the fact that sapogenin and/or sapogenin ester are used as agents for smoothing out wrinkles and fine lines, one of ordinary skill in the art would not reasonably have been motivated to add another compound for the same purpose.

Even though *Besne* teaches in paragraph [0071] that its composition "may comprise other muscle relaxants," muscle relaxants are one of twelve (12) broad categories of compounds that may be added to *Besne*'s composition. *See* paragraphs [0039]-[0092] (emphasis added). Without relying on the present disclosure as a blueprint, the Examiner has no evidence of a suggestion or motivation to pick and choose a muscle relaxant over other types of compounds to be added into *Besne*'s composition.

Even, for purpose of argument, if one of ordinary skill in the art were to choose to add a muscle relaxant into *Besne*'s composition, the Examiner has failed to point to any evidence of a suggestion or motivation to specifically use hexapeptide argireline in combination with at least one other muscle relaxant disclosed in *Besne* to arrive at the composition as presently claimed. The Examiner cites Example 2 disclosed in *Besne* in support of this rejection. However, Applicant respectfully submits that Example 2 does

not teach any composition comprising additional muscle relaxants disclosed in *Besne* besides sapogenin and sapogenin ester, let alone the hexapeptide argireline.

Finally, neither the facts nor the holding of *In re Kerkhoven* applies to this case. In *Kerkhoven*, the applicant claimed a process for preparing a detergent composition comprising mixing two known detergent materials[.]" The court held that the claims at issue requiring "no more than the mixing together" of two conventional detergents to make a third detergent composition set forth "prima facie obvious subject matter." *Kerkhoven*, 205 USPQ 1069, 1072 (emphasis added).

The presently claimed invention, however, does not involve merely mixing two compositions. Instead, to arrive at the presently claimed composition, the Examiner has to point to objective evidence of a suggestion or motivation to pick and choose muscle relaxants over other types of compounds that may be added into *Besne*'s composition and to use the hexapeptide argireline as a requisite component together with at least one other muscle relaxant disclosed in *Besne*. However, as discussed above, the Examiner has failed to do so.

Further, the present specification, in Example 1, indicates that the combination of the at least one peptide, such as Argireline®, with the at least one calcium-channel inhibitor, such as magnesium gluconate, which is different from the at least one peptide, provides unexpectedly superior inhibitory synergistic effect on type-L calcium channels, verapamil site. Paragraphs [096]-[0107]. These facts do not fall within the facts of *Kerkhoven*, where the combination of two detergents simply formed a third detergent.

Accordingly, as the Examiner has not established a *prima facie* case of obviousness, Applicant respectfully requests this rejection be withdrawn.

VIII. § 103(a) Rejection Over The French Patent '344

The Examiner rejects claims 1-26 under 35 U.S.C. § 103(a) as being obvious over French Patent No. 2,838,344 ("the French Patent '344"), which is the equivalent of *Besne*. Office Action, page 6. The Examiner indicates that "the French Patent '344 is currently available as prior art under 35 U.S.C. 102(a), and unlike Besne, the provisos of 35 U.S.C. 103(c) do not currently apply to this rejection over the French Patent '344." *Id.*

Applicants respectfully request this rejection be withdrawn in view of the arguments set forth in section VII above with respect to the section 103(a) rejection over *Besne*.

IX. § 102(a) and (b) Rejections Over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (Formerly Faux-Tox) By BeautyLand"

The Examiner rejects claims 1-5, 12, 13, 15, 16, and 19-26 under 35 U.S.C. § 102(a) and (b) as being anticipated by "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand," each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news." Office Action, pages 6-7. Specifically, the Examiner alleges that "'British Nursing News Online-News Archives', page 3, teaches that a cosmetic product named 'Faux-Tox', a cream, was supplied from New York and was on sale in Edinburgh at least by November 3, 2002." *Id.* at page 6. The Examiner further alleges that "'DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand' teaches a cosmetic product named 'Wrinkle Relax', formerly called 'Faux-

Tox', and gives a copyright date of 2001, indicating that the cosmetic product was on sale in this country at least in the year 2001." *Id.*

Further, the Examiner alleges that as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news," the cosmetic product named "Wrinkle Relax," aka "Faux-Tox" "is comprised of Acetyl Hexapeptide-3 and magnesium ascorbyl." *Id.* at page 7. Therefore, the Examiner concludes that the rejected claims are anticipated by the cited references. *Id.* at page 6. Applicant respectfully disagrees for at least the following reasons.

The Examiner has failed to establish that the cosmetic product named "DDF Wrinkle Relax" or "Faux-Tox" was "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent" under § 102(a), or "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the [present] application" under § 102(b).

Specifically, the Examiner has relied on the November 3, 2002 date appearing on "British Nursing News Online-News Archives," page 3, for sale in Edinburgh, Scotland. However, such a sale did not occur in the U.S., therefore, is not a sale "in this country." Further, the Examiner has relied on the copyright date of 2001 appeared on "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand" for sale in the U.S. However, Applicant respectfully submits that all products sold by BeautyLand under more than 100 categories on its website (http://www.beautyland.com) bear the same copyright date of 2001. Even the products with a flash "New" bear the same copyright date of

2001. *See* a copy of advertisement of an exemplary product, "Biosilk Recovery Treatment," printed out from BeautyLand website. (The copy is enclosed for the Examiner's convenience.) Based on these findings, most likely, the copyright date of 2001 is not an indication of when the product was put on sale. Clearly the company did not put that many products on sale in 2001 alone. It seems more probable that the 2001 copyright has to do with the company, website name, logo, or something not product-specific. Therefore, the copyright date of 2001 appeared on "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand" cannot be used in support of the Examiner's allegation of the sale date in the U.S.

Moreover, neither "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" nor "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news" provides any meaningful date in support of this section 102 rejection.

Accordingly, Applicant respectfully requests this rejection be withdrawn.

X. § 103(a) Rejection Over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (Formerly Faux-Tox) By BeautyLand"

The Examiner rejects claims 8-11 and 13 under 35 U.S.C. § 103(a) as being obvious over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand," each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news." Office Action, pages 7-8. Specifically, the Examiner states that "[a]pplication of the references is the same as in above rejection of claims 1-5, 12, 13, 15, 16, and 19-26." *Id.* at page 7. The Examiner admits that the

"references do not disclose concentrations for the various components present in Wrinkle Relax/Faux-Tox." *Id.* To remedy this deficiency, the Examiner alleges that it would have been obvious to "determine all operable and optimal concentrations for the components of Wrinkle Relax/Faux-Tox." *Id.* at pages 7-8. Applicant respectfully disagrees for at least the following reason.

As discussed above in section IX, the cited references do not support a proper section 102 rejection, *i.e.*, the Examiner has failed to show that they are valid section 102 prior art. Thus, those references cannot serve as valid section 103 prior art. Accordingly, Applicant respectfully requests this rejection be withdrawn.

XI. § 103(a) Rejection Over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (Formerly Faux-Tox) By BeautyLand" in view of *Simon*

The Examiner rejects claims 17 and 18 under 35 U.S.C. § 103(a) as being obvious over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand," each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news" as applied against claims 1-5, 12, 13, 15, 16, and 19-26 above, and further in view of Simon et al. (U.S. Patent No. 5,730,972) ("*Simon*"). Office Action, page 8. Specifically, the Examiner admits that the "references applied in the above rejection do not teach the presence of a UVA-active photoprotective agent." *Id.* To remedy this deficiency, the Examiner relies on *Simon*. *Id.* Applicant respectfully disagrees for at least the following reason.

As discussed above in section IX, the cited references do not support a proper section 102 rejection, *i.e.*, the Examiner has failed to show that they are valid section 102 prior art. Thus, those references cannot serve as valid section 103 prior art. Further, the Examiner's reliance on *Simon* is solely for its teaching of a UVA-Active photoprotective agent, which does not cure this deficiency. Accordingly, Applicant respectfully requests this rejection be withdrawn.

XII. Allowable Subject Matter

Applicant thanks the Examiner for indicating that claims 6 and 7 "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Office Action, page 8.

XIII. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application, and the timely allowance of the pending claims.

If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, he is invited to call the Applicant's undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 2, 2005

By: Reg. No. 41,469
Ningling Wang
Reg. No. 52,412

Attachments:

1. Revised Application Data Sheet;

2. An English translation of the provisional application No. 60/427,575 and a statement that the translation is accurate; and

3. A copy of advertisement of an exemplary product, "Biosilk Recovery Treatment," printed out from BeautyLand website.

4 oz $11.00 Quantity: 1 Order 5.3 oz $12.50 Quantity: 1 Order

Spray Gel
Spray Gel - Alcohol free, desirable for chemically treated hair. No flaking, stickness or buildup.

11 oz $10.00 Quantity: 1 Order

Treatment

Fruit Cocktail
Biosilk Fruit Cocktail, An advanced reconstructing treatment, builds volume and strength, restores softness and smoothness.

11.6 oz. $12.00 Quantity: 1 Order

Recovery Treatment
Biosilk Recovery Treatment,an intense deep penetrating reconstructor that will provide hair with the ultimate in moisture recovery while restructuring the hair. Healing emollients and silk proteins will revitalize dry, damaged and overstressed hair. Hair is left soft and silky with incredible volume, body and healthy shine.

6 oz $12.00 Quantity: 1 Order

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Questions/Comments - E-MAIL US

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